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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/760,917 | 01/16/2001 | Mohamed M. Haq | 50016-2 | 4854 |

58773 7590 07/31/2006

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| EXAMINER | |
|---|---|
| NAJARIAN, LENA | |
| **ART UNIT** | **PAPER NUMBER** |
| 3626 | |

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/760,917 | HAQ, MOHAMED M. | |
| | Examiner | Art Unit | |
| | Lena Najarian | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15,23,29-34 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 23, 29-34, and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Notice to Applicant*

1. This communication is in response to the request for continued examination (RCE) filed 5/12/06. Claims 1-15, 23, 29-34, and 36-38 are pending. Claims 1, 23, 30, 33, and 36 have been amended. Claims 16-22, 24-28, and 35 have been cancelled.

### *Claim Objections*

2. Claim 36 is objected to because of the following informalities: the claim is not dependent on another claim. For purposes of applying prior art, the Examiner considers claim 36 to properly dependent on claim 33. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8, 14-15, 29-34, and 36-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Leet (6,000,828).

(A) Referring to claim 1, Leet discloses a computer system for assisting a physician comprising (col. 16, lines 25-28 of Leet):

computer processor means (col. 1, lines 5-7 of Leet);

data storage means for storing data (Fig. 1 and col. 5, lines 30-47 of Leet);

first means for processing data regarding a patient, a diagnosis regarding the patient, and a treatment plan for the patient, for comparing the data against known patient information and against known medical information; and for using such data to generate alarms if the diagnosis or treatment plan is inappropriate and to provide advice regarding the diagnosis and treatment plan (col. 1, lines 5-11 & 45-49, col. 17, lines 15-20, and col. 3, lines 26-40 of Leet; the Examiner interprets "recommended treatments" to be a form of "advice");

second means for processing data regarding the alarms and advice and for using such data to communicate the alarms and advice to the physician (col. 17, lines 15-20 of Leet; the Examiner interprets "alerting" to be a form of "alarms" and "approved treatment" to be a form of "advice"); and

third means for processing data regarding the treatment plan and using such data to implement the treatment plan (col. 1, lines 32-37 of Leet).

(B) Referring to claim 2, Leet discloses wherein the first means for processing data comprises:

a suggest diagnosis means for processing data using a subset of the patient data to access a suggested diagnosis database to retrieve a suggested diagnosis (col. 3, lines 26-40 of Leet); and

a check diagnosis means for processing data for comparing the diagnosis to the suggested diagnosis and for generating an alarm if there is a substantial difference (col. 17, lines 15-20 of Leet).

(C) Referring to claim 3, Leet discloses wherein the first means for processing data comprises:

a find standard diagnostic criteria means for processing data using a subset of the diagnosis to access a standard diagnosis criteria database to produce a standard diagnosis criteria (col. 3, lines 26-40 of Leet).

(D) Referring to claim 4, Leet discloses wherein the treatment plan includes a prescription and the first means for processing data comprises:

a get drug data means for processing data using a subset of the patient data to retrieve from a pharmacy one or more drugs prescribed for the patient and from the data storage means an identification of other drugs that the patient is taking; and

an interaction checking means for processing data to access a drug interaction database with (a) one or more drugs prescribed for the patient, (b) other drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner interprets "drug order" to be a form of "prescription" and "message" to be a form of "alarm").

(E) Referring to claim 5, Leet discloses wherein the interaction checking means comprises mitigating means for suggesting methods to mitigate the interaction; and alternative recommendation means for suggesting alternative drugs with no interaction (col. 25, lines 18-61 of Leet).

(F) Referring to claim 6, Leet discloses wherein the first means for processing data comprises:

a get patient data means for processing data for accessing the data storage means to retrieve stored data regarding the patient;

a find treatment means for processing data for accessing a treatment protocol database using a subset of the patient data and a subset of the stored patient data to retrieve a recommended treatment protocol (abstract of Leet).

(G) Referring to claim 7, Leet discloses wherein the first means for processing data comprises:

a get patient data means for processing data for accessing the data storage means to retrieve stored data regarding the patient;

a treatment search means for processing data for accessing a treatment recommendation database using a subset of the patient data and a subset of the stored patient data to retrieve a treatment individualization recommendation (col. 12, line 50 – col. 13, line 1 of Leet).

(H) Referring to claim 8, Leet discloses wherein the diagnosis comprises a prescription and the first means for processing data comprises:

a get lab data means for processing data using a subset of the patient data to acquire laboratory results from a laboratory (col. 11, lines 36-40 of Leet);

a find dosage means for processing data for using the lab results, a subset of the patient data, the prescription and data regarding the patient stored on the data storage

means to access a recommended dosage database to produce a recommended dosage for the prescription (col. 18, line 67 – col. 19, line 5 of Leet).

(I) Referring to claim 14, Leet discloses wherein the treatment plan comprises a prescription and the first means for processing data comprises:

a get drug data means for processing data using a subset of the patient data to retrieve from a pharmacy one or more drugs prescribed for the patient and from the data storage means an identification of other drugs that the patient is taking; and

a drug cost means for processing data to access a drug cost database with (a) one or more drugs prescribed for the patient, (b) the other drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication that the patient is spending more on drugs than is necessary and to make a recommendation for a lower cost drug (col. 18, line 49 – col. 19, line 12 and col. 32, lines 35-49 of Leet).

(J) Referring to claim 15, Leet discloses wherein the first means for processing data comprises a check risks means for processing data using a subset of the patient data to access a risk data base to produce a risk reduction recommendation for the patient (abstract, lines 1-9 of Leet; the Examiner interprets "rankings" to be a form of "recommendation").

(K) Referring to claim 29, Leet discloses wherein the data stored on the data storage means comprises:

a suggested diagnosis database (col. 8, lines 10-11 of Leet);

a standard diagnostic criteria database (col. 3, lines 26-40 of Leet);

a drug interaction database (col. 18, line 49 – col. 19, line 12 of Leet);

a treatment protocol database (abstract, lines 1-4 of Leet);

a treatment recommendation database (col. 1, lines 9-11 of Leet);

a recommended dosage database (col. 18, line 67 – col. 19, line 5 of Leet);

a drug cost database (col. 32, lines 35-49 of Leet); and

a risk database (abstract, lines 1-9 of Leet).

(L) Referring to claim 30, Leet discloses wherein the first means has access to one or more of the following (col. 6, lines 5-9 of Leet):

a suggested diagnosis database (col. 8, lines 10-11 of Leet);

a standard diagnostic criteria database (col. 3, lines 26-40 of Leet);

a drug interaction database (col. 18, line 49 – col. 19, line 12 of Leet);

a treatment protocol database (abstract, lines 1-4 of Leet);

a treatment recommendation database (col. 1, lines 9-11 of Leet);

a recommended dosage database (col. 18, line 67 – col. 19, line 5 of Leet);

a drug cost database (col. 32, lines 35-49 of Leet); and

a risk database (abstract, lines 1-9 of Leet).

Insofar as the claim recites "one or more of," it is immaterial whether or not all of the elements are disclosed.

(M) Referring to claim 31, Leet discloses wherein the third means comprises an ICD determination means for processing a subset of the patient data, a subset of the diagnosis and a subset of the treatment plan to determine an ICD (col. 1, lines 23-28, col. 7, lines 39-46, and Table 1 of Leet).

(N) Referring to claim 32, Leet discloses wherein the treatment plan comprises a prescription and an order, the patient data comprises an ICD, and the third means comprises one or more of the following: a print prescription means for processing data for using the prescription to print a prescription form; an inform pharmacy means for processing data for using the prescription to inform a pharmacy of the prescription; a store data means for processing data to store patient data on a hospital computer; an enter order means for processing data to enter the order in a physician order entry system; a save ICD means for processing data to save the ICD in a business office (col. 18, line 49 – col. 19, line 18 and col. 34, lines 16-18 of Leet).

(O) Referring to claim 33, Leet discloses a computerized method for providing assistance to a physician who has gathered data from a patient, made a diagnosis, and prepared a treatment plan, the method being accomplished using a personal communicator, a computer processor coupled to the personal communicator through a communications medium, a data storage medium coupled to the computer processor, and resources coupled to the computer processor, the method comprising (Fig. 1 of Leet):

entering patient data, a diagnosis and a treatment plan into the personal communicator (col. 24, lines 6-7, col. 18, lines 28-36, and col. 25, lines 8-17 of Leet);

comparing the patient data, the diagnosis and the treatment plan against known patient data and against a medical database (col. 18, line 49 – col. 19, line 3 of Leet);

selecting, through the personal communicator, one or more of the following actions based on the comparison:

implementing the treatment plan (col. 18, lines 49-50 of Leet);

displaying an alarm and a recommendation, and allowing the physician to revise the diagnosis and treatment plan (col. 1, lines 5-11 & 32-37 and col. 17, lines 15-20 of Leet).

(P) Referring to claim 34, Leet discloses wherein implementing the treatment plan comprises one or more of the following printing a prescription; informing a pharmacy of the prescription; storing the patient data, the diagnosis, and the treatment plan on a hospital computer; entering an order into a physician order entry system; and saving an ICD in a business office (col. 34, lines 16-18 and col. 18, lines 54-66 of Leet).

(Q) Referring to claim 36, Leet discloses wherein the step of comparing comprises the following actions: checking the accuracy of the diagnosis; reviewing standard diagnostic criteria; checking the appropriateness of prescribed medication; reviewing recommended treatment protocols; reviewing individualization recommendations; recommending dose adjustments; checking for adverse medication interactions; and checking the cost of prescribed medications (col. 3, lines 26-40 and col. 18, line 57 – col. 19, line 13 of Leet).

Insofar as the claim recites "one or more of," it is immaterial whether or not all of the elements are disclosed.

(R) Referring to claim 37, Leet discloses accepting clinical notes regarding the patient (col. 3, lines 36-40 of Leet).

5. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Portwood et al. (5,950,630).

(A) Referring to claim 9, Leet discloses wherein the patient data comprises foods the patient eats, the treatment plan comprises a prescription and the first means for processing data comprises (Table IV of Leet; the Examiner interprets "diet" to be a form of "foods the patient eats"):

a get drug data means for processing data using a subset of the patient data to retrieve from a pharmacy one or more drugs prescribed for the patient and from the data storage means an identification of other drugs that the patient is taking; and

an interaction checking means for processing data to access a database with (a) one or more drugs prescribed for the patient, (b) the other drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner interprets "drug order" to be a form of "prescription" and "message" to be a form of "alarm").

Leet does not disclose that there is a drug/food interaction database.

Portwood discloses drug-food interaction tests (col. 6, lines 63-67 of Portwood).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Portwood within Leet. The motivation for doing so would have been to ascertain if the drug regimen is within recommended ranges and to determine if any drug/food interaction problems exist (col. 6, lines 59-61 of Portwood).

(B) Referring to claim 10, Leet discloses wherein the interaction checking means includes a recommendation means for recommending a drug that will not have an interaction (col. 25, lines 18-61 of Leet).

6. Claims 11-13 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Evans (5,924,074).

(A) Referring to claim 11, Leet discloses wherein the treatment plan comprises a prescription and the first means for processing data comprises:

a get drug data means for processing data using a subset of the patient data to retrieve from a pharmacy one or more drugs prescribed for the patient and from the data storage means an identification of other drugs that the patient is taking; and

a checking means for processing data to access a database with (a) one or more drugs prescribed for the patient, (b) the other drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner interprets "drug order" to be a form of "prescription" and "message" to be a form of "alarm").

Leet does not disclose a radiology/drug interaction database and radiology tests.

Evans discloses the usage of x-rays when prescribing medications (col. 5, lines 13-22 if Evans).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet. The motivation for doing so

would have been for the physician to obtain additional clinical data, such as x-rays before recommending a treatment plan (col. 5, lines 40-46 of Evans).

(B) Referring to claim 12, Leet does not disclose wherein the treatment plan comprises an order for X-rays and the first means for processing data comprises a check X-rays means for processing data using a subset of the patient data to acquire laboratory results from a laboratory and for accessing an X-ray contraindication database with the laboratory results and the order for X-rays to produce a contraindication and to process the contraindication to produce an alarm.

Evans discloses wherein the treatment plan comprises an order for X-rays and the first means for processing data comprises a check X-rays means for processing data using a subset of the patient data to acquire laboratory results from a laboratory and for accessing an X-ray contraindication database with the laboratory results and the order for X-rays to produce a contraindication and to process the contraindication to produce an alarm (col. 5, lines 42-55, col. 12, lines 10-17 of Evans; the Examiner interprets "warning" to be a form of "alarm").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet. The motivation for doing so would have been to alert the physician to investigate the effects of the treatment (col. 12, lines 17-19 of Evans).

(C) Referring to claim 13, Leet does not disclose wherein the check X-rays means for processing data also processes the contraindication to produce a recommendation.

Evans discloses wherein the check X-rays means for processing data also processes the contraindication to produce a recommendation (col. 12, lines 10-34 of Evans).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet. The motivation for doing so would have been to allow the physician to investigate the effects of the medication and select another medication from the list (col. 12, lines 10-34 of Evans).

(D) Referring to claim 38, Leet does not disclose wherein accepting the clinical notes comprises recording a spoken rendering of the clinical notes.

Evans discloses wherein accepting the clinical notes comprises recording a spoken rendering of the clinical notes (col. 9, lines 1-4 of Evans; the Examiner interprets "physician's dictation" to be a form of "spoken rendering of the clinical notes").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet. The motivation for doing so would have been to include patient data in a variety of data types generated by healthcare providers (col. 8, lines 65-66 of Evans).

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Barry et al. (6,081,786).

(A) Referring to claim 23, Leet does not disclose further comprising a personal communicator including a display having a red alert area, where alarms regarding the

potential for a major adverse effect are displayed; and a yellow alert area, where alarms regarding the potential for a minor effect or need for closer monitoring are displayed.

Barry discloses a personal communicator including a display having a red alert area, where alarms regarding the potential for a major adverse effect are displayed; and a yellow alert area, where alarms regarding the potential for a minor effect or need for closer monitoring are displayed (col. 14, lines 16-22 & 43-47 of Barry).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Barry within Leet. The motivation for doing so would have been to provide an instant graphical warning level (col. 14, lines 42-43 of Barry).

### *Response to Amendment*

8. The amendment to the claims filed on 5/12/06 does not comply with the requirements of 37 CFR 1 .121(c) because claim 11's status identifier is incorrect ("currently amended" should be "previously presented").

### *Response to Arguments*

9. Applicant's arguments filed 5/12/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 5/12/06.

(1) Applicant argues that neither Leet nor Vonk teach or suggest comparing data against known patient information and against known medical information, as required by amended claim 1.

(2) Applicant argues that neither Leet nor Vonk teach or suggest comparing patient data, the diagnosis and the treatment plan against known patient data and against a medical database, as required by amended claim 33.

(A) As per these arguments, at col. 17, lines 15-20, Leet teaches "if the actual therapy selected by a physician or other health care provider is not one of the primary or secondary treatments listed in the approved treatments field, then a message is sent to the prescriber alerting him or her to this discrepancy...." The Examiner respectfully submits that the passage suggests the feature of "comparing" since the data entered by the physician must be *compared* to the treatments listed in the approved treatments field for a "message" to be created. In addition, at col. 3, lines 26-40, Leet teaches that recommended treatments (i.e., medical information) are stored in a ranked order and a clinical outcome of an actual treatment selected for each patient is also recorded in memory (i.e., known patient data).

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

In
7-12-06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER